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10/520,965	06/12/2006	Arik Avni	AMDL-0050	4941
7590 Michael P Dunnam Woodcock Washburn One Liberty Place 46th Floor Philadelphia, PA 19103				
EXAMINER				
LEE, ERICA SHENGKAI				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,965

Applicant(s)

AVNI ET AL.

Examiner

Erica Lee

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-41 is/are pending in the application.
- 4a) Of the above claim(s) 8-23 and 26-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) Z is/are allowed.
- 6) ☒ Claim(s) 1-7-9-13-16-22-24-25 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed October 8, 2010 has been entered. Claims 1, 13, 16 and 18 have been amended. Claim 41 is new. Claims 8, 23 and 26-40 were previously withdrawn in response to a restriction requirement. Claims 14 and 15 were previously cancelled. Currently, claims 1-7, 9-13, 16-22, 24-25 and 41 are pending for examination.

Response to Arguments

2. Applicant's arguments with respect to claims 1-7, 9-13, 16-22, 24-25 and 41 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant argues on page 12 that the device of Havriluk (US Pat 5,005,140) does not teach measuring weight force as Havriluk does not teach a conversion of the measured pressures into pounds. Examiner asserts that weight force is not equivalent to "weight bearing" as currently claimed and that the term "weight bearing" is broad enough to encompass other indicators such as force applied to a sensing device. In fact, Examiner cannot find anywhere in the instant application mention of conversion of pressure sensor signals into weight force. There are numerous instances of the phrase "convert received pressure signals into electrical output signals representative of weight bearing" which is also what Havriluk discloses (col. 3, lines 35-36, 55-50; col. 5, lines 28-44).

4. Applicant argues on page 13 that Havriluk also does not disclose identifying specific stages of a gait cycle of the foot. Column 6, lines 16-21 of Havriluk discloses "The closed containers are each provided at locations to sense specific information. For example, in the case of running, it may be desirable to provide several closed containers 410 through 416 positioned at important locations such as the ball of the foot (410), the arch of the foot (414) or the heel of the foot (416)." Since each of these containers have separately distinguished signals through pressure ports 418-424, Havriluk therefore discloses identifying specific stages of a gait cycle of the foot, such as information about the ball of the foot, the arch of the foot, and the heel of the foot.
5. Applicant argues on page 17 that neither Vredenburg et al. (US Pat 3,881,496) nor Rosenberg (US Pat 4,610,253) teach electrical stimulation feedback to stimulate a muscle group. Vredenburg et al. teaches "applying electrical activation currents to muscular or nervous tissues for stimulation locomotion" (col. 2, lines 5-6) and Rosenberg teaches that a force sensor system for use in monitoring weight bearing may also comprise a pressure transducer 244 for converting the pressure at each respective port into an electrical signal which is then used to actuate an electrical indicator 250 (col. 4, lines 19-30), which be obvious to one of ordinary skill in the art at the time the invention was made as being used to deliver electrical stimulation.
6. The 35 U.S.C. 112, second paragraph rejections of claims 16, 18-22 and 24-25 have been withdrawn.

Priority

7. Acknowledgement is made of Applicant's claim for priority based on an international application PCT/IL03/000572 filed on July 10, 2003. It is noted, however, that Applicant has not filed a certified copy of the international application as required by 37 CFR 1.495(b) because the international application has not yet been received from the International Bureau (IB).
8. Receipt of papers is acknowledged for Applicant's claim for priority based on a provisional application 60/395,127 filed on July 11, 2002.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7, 9-13, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Amended claim 1 now recites "provides feedback to affect movement at said location" in line 12, where it is unclear whether the location is "a location" of line 2, or "a location" of line 6.

12. Claims 2-7, 9-13, 16 and 17 are rejected for being dependent on claim 1.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 16 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253).

15. Regarding claims 1, 16 and 41, Rosenberg discloses a force sensor system for use in monitoring weight bearing at a location (foot) on a person, comprising: a plurality of independent, non-overlapping pockets 22 inflated with liquid ("water" col. 2, lines 53-61) forming the interior of at least one flexible pouch (figs. 1, 6) placed at or near said location; a plurality of tubes 41, wherein at least one tube allows flow of liquid in and out of each of the pockets to a location 32 remote from the pouch; a plurality of pressure sensors remote from the pouch 244 (fig. 7; "ports 43 may thus be connected to an external device, such as a signal, alarm or control, as will be described below particularly with reference to figure 7" col. 3, lines 22-28) connected to said pockets through said tubes, wherein each pressure sensor is disposed to detect the pressure applied to at least one pocket, each pressure sensor converts received pressure signals to electrical output signals representative of the weight bearing on the location (col. 4, lines 19-30); and a control unit ("processor 248") that receives the electrical output signals as input signals and provides feedback ("electrical indicator 250"; "vibrator 252"; "visual alarm 254"; "audio alarm 256"; "display unit 258" col. 4, lines 25-30) obvious to one of ordinary skill in the art to affect movement at said location since Rosenberg

discloses utilizing additional feedback systems providing discomfort ("discomfort-generator 3") where it causes the patient to "shift weight in the best manner to relieve this discomfort" (col. 3, lines 19-20). Rosenberg also discloses this control unit as being part of one of a weight bearing biofeedback system ("vibrator 252"; "visual alarm 254"; "audio alarm 256"; "display unit 258") and an electrical stimulation system ("electrical indicator 250" col. 4, lines 25-30).

16. Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Toms (US Pat 6,036,660).

17. Regarding claims 4, 5 and 9, Rosenberg discloses claimed invention but does not disclose the flexible pouch comprises two outer layers of fabric sheets, the outer layers of sheets being welded together in a welding pattern using a sealing agent; where the said sealing agent comprises an RF-weld, and the outer layers of fabric sheets comprise a fabric base and a polyurethane coating. Toms teaches a flexible pouch comprising two outer layers of fabric sheets comprising a fabric base and a polyurethane coating, the outer layers of sheets being welded together in a welding patterning using an RF-weld sealing agent 5 (fig. 2; col. 4, lines 33-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rosenberg to include the two outer layers of fabric sheets comprised of a fabric base and a polyurethane coating, as well as welding together the fabric sheets using an RF-weld sealing agent as taught by Toms in order to provide a more air tight structure and resistance to deformation from air pressures (col. 4, lines 34-38).

18. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Toms (US Pat 6,036,660) and in further view of McEwen et al. (US PG Pub 2003/0036771).

19. Regarding claim 6, Rosenberg discloses claimed invention except for the outer layers of fabric sheets comprise a fabric base and a polyvinylchloride coating. McEwen et al. discloses a gas filled bladder formed from polyester fabric with a polyvinylchloride coating ([0050], lines 10-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rosenberg to include the polyvinylchloride coated fabric as taught by McEwen et al. in order to provide a flexible gas impermeable bladder layer.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Rechin et al. (US Pat 6,145,142).

21. Havriluk discloses claimed invention but does not expressly disclose the pockets comprise at least two layers of translucent film. Rechin et al. discloses an inflatable bladder being comprised of a translucent material (claim 23). It would have been an obvious matter of design choice to make the pockets comprising at least two layers of translucent film as taught by Rechin et al., since Applicant has not disclosed that translucent film solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with pockets comprising at least two layers of translucent film.

22. Claims 3, 10, 18, 20, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Havriluk (US Pat 5,005,140).

23. Regarding claims 3, 10 and 18, Rosenberg discloses the pouch is inside a sock and does not expressly disclose the pouch comprises a flexible insole worn inside a shoe. Havriluk teaches a similar force sensor system for the foot that is a flexible insole worn inside a shoe (col. 6, lines 13-16), where the flexible insole contains a first inflatable pocket in the heel region of the insole and a second inflatable pocket in the forefoot region of the insole 416 and 410 (fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rosenberg such that the pouch was a flexible insole worn inside a shoe as taught by Havriluk in order to provide a sensing system that would not require wearing fabrics that may wear out quicker.

24. Regarding claim 20, Havriluk discloses the inflatable pockets include extensions connecting the insole and the tubes 418-424 (fig. 8), which would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rosenberg to incorporate the extensions as taught by Havriluk in order to provide more tube length between the pockets and the electrical stimulator and reduce tension strain.

25. Regarding claims 21, 24 and 25, Rosenberg discloses the electrical signals converted from the pressure sensors by the control unit could be used in

an electrical stimulation system ("electrical indicator 250" col. 4, lines 25-30) but does not expressly disclose a controller that activates the stimulator to deliver stimulation to a first muscle group in response to input signals from a heel pressure sensor and activating said stimulator to deliver stimulation to a second muscle group in response to input signals from a forefoot pressure sensor. However, Rosenberg discloses both a heel and forefoot pressure sensor 244 corresponding to each respective pouch (fig. 2) and since Rosenberg also discloses the invention is to teach the patient to shift his weight in the best manner to relieve sensed discomfort at specific locations (col. 3, lines 18-20), it would have been obvious to one of ordinary skill in the art at the time the invention was made that the electrical stimulation system would not comprise merely one electrical indicator 250 but several, to help the patient learn the best way to relieve any sensed stimulation, the orientation of the electrical indicators designed to be similar to that of the discomfort-generator 3 (fig. 1) where different muscle groups are stimulated, such as the anterior or posterior muscles of the tibia.

26. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Goldman (US Pat 5,775,332).

27. Regarding claim 17, Rosenberg discloses multiple pockets 22 at various locations of the foot (fig. 2) suitable for indentifying specific stages of a gait cycle of the foot, and an electrical stimulation system (fig. 7). Rosenberg does not mention an

electronic orthosis but Goldman teaches it is well known in the art to associate an electronic orthosis with a sensor system, and to use electronic cues from the sensor system to activate the electronic orthosis (col. 8, lines 20-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rosenberg to include an electronic orthosis as taught by Goldman in order to provide better ambulation in patients (col. 8, lines 27-29).

28. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Havriluk (US Pat 5,005,140) and further in view of Goldman (US Pat 5,775,332).

29. Regarding claim 22, Goldman teaches the degree of stimulation to the patient can increase in intensity with weight increase (col. 12, lines 56-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rosenberg to include the relationship between the stimulation and pressure measurements as taught by Goldman in order to better notify the patient of different degrees of weight bearing.

30. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Hochburg (US Pat 4,989,615).

31. Regarding claim 2, Rosenberg does not expressly disclose the exact mechanics of providing a pressurized plurality of pockets such as a plurality of valves open to allow inflation and deflation of said pockets and closing to allow closed system operation of

said pockets. Hochburg teaches a force sensor system comprising a plurality of independent, non-overlapping pockets inflated with fluid and a plurality of valves remote from the pockets connected to the pockets through the tubes operating in a manner as claimed (fig. 4; col. 4, lines 6-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made modify Rosenberg to include the valves as taught by Hochburg to provide a means of pressurizing the pockets (col. 2, lines 41-43).

32. Claims 11, 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (US Pat 4,610,253) in view of Havriluk (US Pat 5,005,140) and further in view of Hochburg (US Pat 4,989,615).

33. Regarding claims 11 and 12, Rosenberg provides embodiments for sensing pressure forces from the foot and buttocks of a patient to prevent pressure sores, but it is also equally feasible for pressure sores to be a risk in other locations of the body such as the knee or the palm, in which a mechanism for securing the device would be necessary. Hochburg discloses a flexible wrap capable of being worn around a knee or a palm (fig. 4); when worn around the knee, the flexible wrap comprises two adhesive strips capable for tightly securing the wrap on the anterior aspect of the knee joint (col. 3, lines 22-28). Hochburg does not expressly disclose a latch for tightly securing the wrap around the thenar and the hypothenar, but it is well known in the art to use a latch, such as a belt buckle, in conjunction with two straps, for tightly securing a wrap around a body part. Therefore, it would have been obvious to one of ordinary skill in the

art at the time the invention was made to modify Rosenberg to include the adhesive strips and latch as taught by Hochburg in order to provide a more secure attachment to the flexible wrap around the knee and the palm.

34. Regarding claim 19, Rosenberg does not expressly disclose the exact mechanics of providing a pressurized plurality of pockets such as a plurality of valves open to allow inflation and deflation of said pockets and closing to allow closed system operation of said pockets. Hochburg teaches a force sensor system comprising a plurality of independent, non-overlapping pockets inflated with fluid and a plurality of valves remote from the pockets connected to the pockets through the tubes operating in a manner as claimed (fig. 4; col. 4, lines 6-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made modify Rosenberg to include the valves as taught by Hochburg to provide a means of pressurizing the pockets (col. 2, lines 41-43).

Allowable Subject Matter

35. Claim 7 is allowed.

Conclusion

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **It is clear the amendment of claim 1 has necessitated the new grounds of rejection presented in this Office action. Furthermore, though claim**

18 appears to have been amended in response to the 35 U.S.C. 112, second paragraph rejection, the inclusion of additional limitations necessitated reconsideration of the references as applied and the new grounds of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erica Lee whose telephone number is (571)270-1480. The examiner can normally be reached on Monday through Friday, 8:30am-6pm, EST; alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erica Lee/
Examiner, Art Unit 3766

/Mark W. Bockelman/
Primary Examiner, Art Unit 3766